

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	No.
Plaintiff,	)	
	)	
v.	)	Judge
	)	
MICHAEL J. REINSTEIN,	)	
	)	JURY TRIAL DEMANDED
Defendant.	)	

**COMPLAINT**

The United States of America, by Gary S. Shapiro, Acting United States Attorney for the Northern District of Illinois, for its complaint states:

**Jurisdiction And Venue**

1. This action arises under the False Claims Act, as amended, 31 U.S.C. §§ 3729-33, and under common law theories of payment by mistake of fact, unjust enrichment, and fraud. This court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

2. Venue is proper in the Northern District of Illinois pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a), because the defendant resides and transacts business in this district.

**Parties**

3. Plaintiff, the United States of America, acting through the Department of Health and Human Services (HHS), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act (Act), 42 U.S.C. §§ 1395 *et seq.*, (Medicare), and Grants to States for Medical Assistance Programs pursuant to Title XIX of the Act, 42 U.S.C. §§ 1396 *et seq.*, (Medicaid).

4. Defendant Michael J. Reinstein (Reinstein) resides in Skokie, Illinois, and was licensed by the State of Illinois as a physician at all times relevant to this complaint. Since at least 1999, Reinstein has maintained an office at 4755 North Kenmore Avenue in Chicago, Illinois.

### **The Law**

5. The False Claims Act (FCA) provides, in pertinent part that:

(a) Any person who —

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]

(3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government; . . .

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

(b) For purposes of this section, the terms “knowing” and “knowingly” mean that a person, with respect to information —

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(a), (b) (FCA, pre-2009 amendments). The False Claims Act was amended by the Fraud Enforcement and Recovery Act of 2009, Public Law 111-21. 31 U.S.C. § 3729(a)(1)(A), (B) (reflecting changes to the wording of the pre-2009 FCA provisions previously found at 31 U.S.C. § (a)(1), (2) and (3)). *See also* 28 C.F.R. § 85.3(a)(9) (detailing current civil penalties of not less than \$5,500 and not more than \$11,000 for violations of the FCA).

6. The Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

7. The Anti-Kickback Act prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical services, including services provided under the Medicare and Medicaid programs:

(b) Illegal remunerations

\* \* \*

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering or arranging for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, to civil monetary penalties of \$50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

8. In 2010, Congress amended the Anti-Kickback Act to clarify that “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].” Patient Protection and Affordable Care Act of 2010 (PPACA), Pub. L. No. 111–148 § 6402(f), 124 Stat. 119, 759 (to be codified at 42 U.S.C. § 1320a–7b(g)).

### **The Medicare and Medicaid Programs**

9. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A. Part B of the Medicare Program authorizes payment of federal funds for medical and other health

services, including without limitation physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173. Part D provides prescription drug benefits for Medicare beneficiaries. Beneficiaries can obtain the Part D drug benefit by joining a Prescription Drug Plan for drug coverage only, or they can join a Medicare Advantage plan that covers both medical services and prescription drugs.

10. HHS is responsible for the administration and supervision of the Medicare program. The Centers for Medicare and Medicaid Services (CMS) is an agency of HHS and is directly responsible for the administration of the Medicare program.

11. Medicare enters into provider agreements with providers and suppliers to establish their eligibility to participate in the program. In order to be eligible for payment under the program, physicians must certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

CMS Forms 855I.

12. Reinstein was obligated to make and comply with this certification in order to be eligible to submit claims to Medicare. Pharmacies must make a similar certification to be eligible to submit claims to Medicare. CMS Form 855S.

13. As detailed below, Reinstein submitted and/or caused claims to be submitted to Medicare Part B for services he purportedly provided to beneficiaries and caused the submission of claims to Medicare Part D for prescription drugs he prescribed to his patients.

14. The Medicaid program was also created in 1965 as part of the Social Security Act, which authorized federal grants to states for medical assistance to low-income, blind, or disabled persons, or to members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the federal and state governments. CMS administers Medicaid on the federal level. Within broad federal rules, each state determines eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. The states directly pay providers, with the states obtaining the federal share of the payment from accounts that draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). The federal share of Medicaid expenditures varies by state and can fluctuate annually.

15. In Illinois, providers participating in the Medicaid program submit claims for services rendered to recipients to the Illinois Department of Healthcare and Family Services for payment.

16. As detailed below, Reinstein submitted and/or caused claims to be submitted to Medicaid for services he purportedly provided to Medicaid recipients and caused the submission of claims to Medicaid for prescription drugs he prescribed to his patients.

17. Compliance with the Anti-Kickback Act is a condition of payment for both Medicare and Medicaid.

## **Specific Allegations**

### **A. Reinstein's Psychiatric Practice**

18. From 1973 through the present, Reinstein has provided psychiatric services to patients in Chicago and the surrounding area. Since at least 1999, Reinstein's office has been located in the Uptown neighborhood of Chicago, which is home to the densest concentration of mentally ill nursing home residents in Illinois. As part of his practice, Reinstein routinely prescribes for his patients atypical antipsychotics and other medications used in the treatment of psychiatric disorders.

19. At all relevant times Reinstein knew that, because most of his patients are indigent nursing home residents, the medications he prescribed were dispensed by pharmacies that submitted claims for the prescriptions to Medicaid and, after January 1, 2006, to Medicare Part D.

20. During this same period, Reinstein submitted and/or caused to be submitted to both Medicaid and Medicare claims for the "pharmacologic management" of his patients, which were billed under the Current Procedural Terminology (CPT) Code 90862. CPT Code 90862 is to be used by physicians when billing for a patient encounter that is focused on the prescribing and monitoring of psychopharmacologic agents. Because psychopharmacologic agents are potent medications with frequent serious side effects, a psychiatrist billing a patient encounter under CPT Code 90862 is expected to engage in a substantive evaluation of the patient's medical and psychiatric condition in order to properly manage their medication needs.

21. During the relevant time period, Reinstein purportedly provided pharmacologic management to patients at more than 30 different nursing homes and long-term care facilities.

22. Prior to August 2003, Reinstein prescribed Clozaril, an atypical antipsychotic manufactured by Novartis, for many of his patients. Clozaril was the trade name for the clozapine molecule that Novartis had patented. For many years prior to August 2003, Novartis paid Reinstein to promote Clozaril.

23. While clozapine has been shown to be effective for treatment-resistant forms of schizophrenia, clozapine is also known to cause numerous serious side effects, including agranulocytosis (a condition involving a potentially deadly decrease in white blood cells), seizures, myocarditis (inflammation of the heart muscle), and increased mortality in elderly patients. As a result of these serious potential side effects, clozapine is generally considered a drug of last resort, particularly for elderly patients. Despite the potential side effects and clozapine's status as a drug of last resort, Reinstein often had more than 1,000 individual patients on Clozaril at any given time prior to August 2003.

24. Novartis's patent for Clozaril expired in 1998. Generic forms of clozapine became available that same year. Despite the availability of generic, bioequivalent alternatives to Clozaril, Reinstein resisted pharmacy and drug company efforts to switch his patients to generic clozapine and continued to be the largest prescriber of Novartis's Clozaril to Medicaid recipients in the United States. In 2000 and 2001, Reinstein prescribed more Clozaril to Medicaid recipients than the next nine top Clozaril-prescribing physicians in the United States combined.

25. In or about July 2003, Novartis notified Reinstein that it would be withdrawing its "support" for Clozaril. The regular payments Novartis had been making to Reinstein ended soon thereafter.

**B. Kickbacks Solicited and Received by Reinstein in Exchange for Prescribing Clozapine to His Patients**



26. IVAX Corporation is a Delaware corporation that previously had its headquarters in Miami, Florida. IVAX Pharmaceuticals, Inc. (IVAX), a Florida corporation, is a subsidiary of IVAX Corporation. IVAX manufactured and sold generic clozapine in Illinois and throughout the United States.

27. Because of the large number of psychiatric patients for whom Reinstein prescribed medications, particularly Clozaril, IVAX wanted to find a way to persuade Reinstein to switch his patients from Clozaril to IVAX's generic clozapine.

28. In early 2003, employees of IVAX reached out to Reinstein in an effort to induce him to switch his patients to IVAX's generic version of clozapine. Prior to August 2003, Reinstein had continued to refuse to switch his patients from Clozaril to generic clozapine. However, in or about August 2003, soon after Novartis informed Reinstein that it would be withdrawing its "support" to him for Clozaril, Reinstein finally agreed to switch his patients to generic IVAX clozapine if IVAX agreed to: pay Reinstein \$50,000 (\$4,166 per month) under a one-year "consulting agreement"; pay Reinstein's nurse, Lynne Jones, to speak on behalf of clozapine; and fund a clozapine research study by a Reinstein-affiliated entity known as Uptown Research Institute. IVAX agreed, and at a meeting with IVAX employees in Chicago, Illinois, on August 19, 2003, IVAX confirmed the remuneration it was offering Reinstein, and Reinstein confirmed his agreement to switch his patients from Clozaril to IVAX's clozapine. After reaching this kickback agreement with IVAX, Reinstein immediately began switching his patients from Clozaril to IVAX's clozapine.

29. After Reinstein switched his patients from Clozaril to IVAX's clozapine beginning in August 2003, Reinstein became the largest prescriber of generic clozapine in the United States. Reinstein's inordinate prescribing of clozapine stands in stark contrast to its extremely limited use

by other physicians. Clozapine is one of the least-prescribed atypical antipsychotics in the United States. During the period in which Reinstein was soliciting and accepting kickbacks from IVAX (and later, as alleged below, from Teva Pharmaceuticals USA, Inc.), approximately four percent of all schizophrenia patients receiving atypical antipsychotics received clozapine. The use of clozapine in nursing homes, where Reinstein focuses his practice, is even more limited. A study done by the United States Department of Health and Human Services found that, in 2007, clozapine was prescribed to less than two percent of nursing home residents for whom claims had been submitted to Medicare for an atypical antipsychotic. During the period in which Reinstein was soliciting and accepting kickbacks to prescribe clozapine, Reinstein had more than fifty percent of his patients on clozapine. At just one nursing home, Reinstein had seventy-five percent of the residents (three hundred out of four hundred) on clozapine.

30. Beginning in 2003 and continuing through 2006, Reinstein requested and IVAX provided additional direct and indirect remuneration to Reinstein and his associates in order to ensure that Reinstein continued to prescribe clozapine to his patients, including but not limited to:

- a. In February 2004, Reinstein traveled to IVAX's headquarters in Miami, Florida, at IVAX's expense. Reinstein asked that IVAX also pay airfare, lodging, meals, and entertainment expenses for Reinstein's wife, a Chicago pharmacy owner, the pharmacy owner's wife, Reinstein's nurse, his accountant and her spouse, and his administrative assistant and her spouse, to travel with Reinstein to Miami. IVAX complied with this request. During this trip, IVAX paid for Reinstein and his entourage to go on a fishing trip and also picked up the check for at least one dinner costing more than \$1,000.

- b. In February 2004, Reinstein asked IVAX to provide him with free, IVAX-manufactured medication for Reinstein's personal use. IVAX complied with this request.
- c. In or about August 2004, Reinstein requested and IVAX renewed its \$50,000 "consulting agreement" with Reinstein, and also renewed its similar agreement with Reinstein's nurse.
- d. In March 2005, IVAX again paid airfare, lodging, meals, and entertainment expenses for Reinstein, his wife, a Chicago pharmacy owner, the pharmacy owner's wife, Reinstein's nurse, his accountant and her spouse, and his administrative assistant and her spouse, to travel with Reinstein to Miami. During this trip, IVAX paid for Reinstein and his entourage to go on a \$800 boat cruise, a golf outing, and at least two dinners costing more than \$1,400 each.
- e. In or about October 2005, Reinstein requested and IVAX renewed its \$50,000 "consulting agreement" with Dr. Reinstein.
- f. From 2003 through 2006, Reinstein repeatedly asked IVAX to pay for tickets to professional sporting events for Reinstein and his associates. IVAX complied with these requests.

31. On January 26, 2006, IVAX Corporation merged with, and became a wholly-owned subsidiary of an Israeli company, Teva Pharmaceutical Industries, Ltd. Within Teva Pharmaceutical Industries, Ltd., the direct corporate parent of IVAX is Teva Pharmaceuticals USA, Inc. (Teva). At all times relevant to this complaint, Teva continued to market and sell clozapine in Illinois and elsewhere.

32. In the months prior to IVAX merging with Teva, in or about April 2005, Reinstein had begun switching large numbers of his patients off of IVAX/Teva's clozapine and placing them on Fazaclo, a dissolvable form of clozapine manufactured by a competitor of IVAX/Teva. By January 2006, Reinstein had reduced the number of patients for whom he was prescribing IVAX/Teva clozapine by about fifty percent.

33. Teva's sales representatives and executives were concerned with the reduction in Reinstein's prescribing of clozapine and attempted to find ways to induce Reinstein to prescribe more clozapine.

34. In April 2006, Teva paid airfare, lodging, meals, and entertainment expenses for Reinstein, a professional associate of Reinstein, Reinstein's wife, his nurse and a guest, his accountant and her spouse, and his administrative assistant and her spouse, to travel with Reinstein to Miami. During this trip, Teva paid for Reinstein and his entourage to go on a \$2,300 boat cruise and at least two dinners costing more than \$1,700 each.

35. At a meeting held during Reinstein's April 2006 trip to Miami, Teva employees asked Reinstein what Teva could do to induce Reinstein to prescribe more clozapine for his patients. Reinstein responded that Teva should hire an associate of his from Chicago, Kim Nguyen (Nguyen). Teva agreed to Reinstein's demand and hired Nguyen in May 2006. In the months immediately after Teva hired Nguyen, Reinstein put several hundred patients back on Teva's clozapine.

36. Reinstein's so-called consulting agreement with Teva expired on August 31, 2006. In or about March 2007, Reinstein pressed Teva's sales representative for a renewal of the consulting agreement. In April 2007, Reinstein and Teva agreed to a new, one-year, \$50,000

“speaker agreement” that was made retroactive to November 2006. Reinstein and Teva entered into new, annual “speaker agreements” in or about June 2008, and again in or about June 2009.

37. On November 3, 2009, Teva made what turned out to be its last payment to Reinstein pursuant to a “speaker agreement.”

38. On November 10, 2009, an article questioning the appropriateness of Reinstein’s use of clozapine appeared in the Chicago Tribune. Shortly after this article appeared, Reinstein contacted Teva and asked that it no longer pay him pursuant to the “speaker agreement.”

39. Teva continued to employ Nguyen until July 15, 2011.

### **False Claims Reinstein Submitted and Caused to be Submitted**

#### **A. Claims to Medicaid and Medicare for Clozapine Prescriptions**

40. With respect to the clozapine that Reinstein prescribed as a result of soliciting and receiving illegal remuneration in violation of the Anti-Kickback Act, Reinstein knew that, because most of his patients are indigent nursing home residents, the medications he prescribed were dispensed by pharmacies that submitted claims for the prescriptions to Medicaid and, after January 1, 2006, to Medicare Part D. Because Reinstein’s clozapine prescriptions were generated by kickbacks, claims to Medicaid and Medicare for reimbursement for these prescriptions were materially false for purposes of the FCA, and Reinstein’s conduct in knowingly causing the submission of these claims violated 31 U.S.C. § 3729(a)(1) (pre-2009 amendments) and 31 U.S.C. § 3729(a)(1)(A) (current version of FCA). All of these claims fall within the FCA’s ten-year statute of limitations. *See* 31 U.S.C. § 3731(b)(2).

41. Medicaid received and paid claims from various pharmacies for clozapine prescriptions written by Reinstein between August 2003 through July 15, 2011, as a result of the

illegal kickbacks he solicited and received from IVAX and Teva. Medicare Part D also received and paid claims for clozapine prescriptions written by Reinstein between January 1, 2006, and July 15, 2011, as a result of the illegal remuneration he solicited and received from IVAX and Teva. The individual claims that Medicaid and Medicare paid are not detailed here to protect the confidential patient information contained therein, and because the claims are too voluminous to summarize here. Contemporaneously with the filing of this complaint, Reinstein will be served with discs containing spreadsheets detailing all of the false and/or fraudulent clozapine prescription claims that were paid by Medicaid and Medicare Part D during the relevant period. For each of the over 100,000 Medicaid claims generated by the kickbacks Reinstein solicited and received, the spreadsheet will include fields identifying:

- Recipient Name
- Recipient ID
- Provider Name
- Provider ID
- Date of Service
- Provider Charge Amount
- Net Liability Amount
- Professional Fee Amount
- NDC Number
- Prescription Number
- Drug Quantity
- Number of Refills Authorized
- Payee ID
- Drug Label Name
- Drug Generic Name
- Drug Brand Name

For each of the over 40,000 Medicare Part D prescription claims generated by the kickbacks Reinstein solicited and received, the spreadsheet will include fields identifying:

- Beneficiary HICN
- Beneficiary Name
- Prescription Drug Event (PDE) Claim Control Number

- PDE Patient Paid Amount
- PDE LICS Amount
- PDE CPP Amount
- Total Paid Plain Government Beneficiary - Other
- PDE Dispensing Fee
- PDE Ingredient Cost Amount
- PDE Sales Tax
- PDE GDCB Amount
- PDE GDCA Amount
- NDC Number
- Drug Product Name
- Generic Name
- Date of service
- Provider ID
- Provider Name
- Prescriber ID
- Prescriber Name

**B. Claims to Medicaid and Medicare for CPT Code 90862 - Pharmacologic Management**

42. For the patients for whom Reinstein prescribed clozapine between August 2003 and July 15, 2011, as a result of illegal kickbacks, Reinstein also submitted and/or caused to be submitted to both Medicaid and Medicare claims for “pharmacologic management” of those patients, which was billed under CPT Code 90862 (which is defined as “prescription, use, and review of medication”). Reinstein did not engage in meaningful pharmacological management, because Reinstein’s prescribing decisions for his clozapine patients were based on the kickbacks he received from IVAX and Teva rather than Reinstein’s independent medical judgment or the individual needs of his patients. Accordingly, the CPT Code 90862 claims Reinstein submitted to Medicaid and Medicare for patients he had on clozapine between August 2003 and July 15, 2011, were materially false for purposes of the FCA, and Reinstein’s conduct in submitting and/or causing the submission of these claims violated 31 U.S.C. § 3729(a)(1) (pre-2009 FCA) and 31 U.S.C. §

3729(a)(1)(A) (current FCA). All of these claims fall within the FCA’s ten-year statute of limitations. *See* 31 U.S.C. § 3731(b)(2).

43. Medicaid and Medicare both paid CPT Code 90862 claims submitted by Reinstein for “pharmacologic management” he purportedly provided to patients he had on clozapine between August 2003 and July 15, 2011. The individual claims that Medicaid and Medicare paid are not detailed here to protect the confidential patient information contained therein, and because the claims are too voluminous to summarize here. Contemporaneously with the filing of this complaint, Reinstein will be served with discs containing spreadsheets detailing all of the false and/or fraudulent CPT Code 90862 claims that were paid by Medicaid and Medicare during the relevant period. For each of the over 40,000 Medicaid claims, the spreadsheet will include fields identifying:

- Recipient Name
- Recipient ID
- Provider Name
- Provider ID
- Payee Name
- Payee ID
- Date of Service
- Place of Service
- Diagnosis Code
- Procedure Code
- Total Units
- Allowed Units
- Provider Charge Amount
- Net Liability Amount

For each of the over 10,000 Medicare claims, the spreadsheet will include fields identifying:

- Provider Name
- Provider Number
- Provider NPI
- Claim Number
- HIC Number
- Beneficiary Name
- Date of Service



- Claim Submission Date
- Date Claim was Paid
- CPT Code
- Amount Submitted
- Amount Allowed
- Amount Paid to Provider

### **Count I**

#### **False Claims Act, 31 U.S.C. § 3729(a)(1)**

#### **Causing the Submission of False Claims to Medicaid and Medicare for Services Rendered as a Result of Kickbacks**

44. Plaintiff incorporates by reference paragraphs 1-43 of this complaint as if fully set forth.

45. Defendant knowingly caused false claims for payment or approval to be presented to the United States in violation of 31 U.S.C. § 3729(a)(1) (pre-2009 amendments) and 31 U.S.C. § 3729(a)(1)(A) (current version of FCA) when he caused the submission of claims to Medicaid and Medicare for clozapine prescriptions the defendant wrote as a result of kickbacks and/or illegal remuneration in violation of the Anti-Kickback Act.

46. By virtue of the false and/or fraudulent claims made by the defendant, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation.

## **Count II**

### **False Claims Act, 31 U.S.C. § 3729(a)(1)**

#### **Submitting and/or Causing the Submission of False Claims to Medicaid and Medicare for CPT Code 90862**

47. Plaintiff incorporates by reference paragraphs 1-43 of this complaint as if fully set forth.

48. Defendant knowingly submitted and/or caused false claims for payment or approval to be presented to the United States in violation of 31 U.S.C. § 3729(a)(1) (pre-2009 amendments) and 31 U.S.C. § 3729(a)(1)(A) (current version of FCA) when he submitted and/or caused the submission of claims to Medicaid and Medicare for CPT Code 90862 for patients for whom Reinstein was prescribing clozapine as a result of illegal kickbacks.

49. By virtue of the false or fraudulent claims made by the defendant, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation.

## **Count III**

### **Payment Under Mistake of Fact**

50. Plaintiff incorporates by reference paragraphs 1-43 of this complaint as if fully set forth.

51. This is a claim for the recovery of monies paid by the United States and the State of Illinois to the defendant as a result of mistaken understandings of fact.

52. The false claims which defendant submitted and/or caused to be submitted to the United States' and the State of Illinois' agents were paid by the United States and the State of Illinois based upon mistaken or erroneous understandings of material fact.

53. The United States and the State of Illinois, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of defendant's certifications and representations, paid defendant certain sums of money to which he was not entitled, and defendant is thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

#### **Count IV**

##### **Common Law Fraud**

54. Plaintiff incorporates by reference paragraphs 1-43 of this complaint as if fully set forth.

55. Defendant made material and false representations in submitting claims to the United States and the State of Illinois, with knowledge of their falsity or reckless disregard for their truth, with the intention that the United States and State of Illinois act upon the misrepresentations to their detriment. The United States and State of Illinois acted in justifiable reliance upon defendant's misrepresentations by making payments on the false claims.

56. Had the true facts been known to the United States and the State of Illinois, defendant would not have received payments for his false and fraudulent claims.

57. By reason of these payments, the United States has been damaged in an amount to be determined at trial.

## **Count V**

### **Unjust Enrichment**

58. Plaintiff incorporates by reference paragraphs 1-43 of this complaint as if fully set forth.

59. This is a claim for the recovery of monies by which the defendant has been unjustly enriched.

60. By directly or indirectly obtaining government funds to which he was not entitled, defendant was unjustly enriched, and is liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

### **Prayer For Relief**

WHEREFORE, plaintiff, United States of America requests that judgment be entered in its favor and against defendant as follows:

1. On the First and Second Counts under the False Claims Act for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Third, and Fifth Counts, for payment by mistake and unjust enrichment, for the damages sustained and/or amounts by which the defendant was unjustly enriched or by which defendant retained illegally obtained monies, plus interest, costs, and expenses, and all such further relief as may be just and proper.

3. On the Fourth Count, for common law fraud, for compensatory and punitive damages in an amount to be determined, together with costs and interest, and for all such further relief as may be just and proper.

Respectfully submitted,

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Acting United States Attorney

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**Office of Inspector General**  
**Illinois Department of Healthcare and Family Services**

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Pat Quinn  
*Governor*

Bradley K. Hart  
*Inspector General*

November 16, 2012

Michael Reinstein  
[REDACTED]

**NOTICE OF MEDICAID PAYMENT SUSPENSION**

Dear Michael Reinstein:

The purpose of this letter is to notify you that your Medicaid payments have been fully suspended as of the date of this letter, pursuant to 42 C.F.R. Section 455.23, 305 ILCS 5/5-1 et. seq. and 89 Ill. Adm. Code Sections 104.1 et. seq. and 140.1 et. seq. The Office of Inspector General (OIG), Department of Healthcare Family Services, is responsible for the decision to suspend your Medicaid payments.

The suspension of your Medicaid payments occurs pending an investigation of a credible allegation of fraud. Specifically, the suspension is based on the following:

- Credible allegation the Provider received illegal kickbacks from pharmaceutical companies and submitted false claims to Medicaid for medications.
- Credible allegation of false statements made concerning the provision of "pharmacologic management" for your patients in 30 area nursing homes and long-term care facilities.

The suspension is temporary. The suspension may last up to 180 days from the date of this letter, and may be extended beyond 180 days under certain circumstances.

You have the right to submit a written rebuttal statement addressing why the suspension should be terminated. You may include with this statement any evidence you believe is pertinent to why the

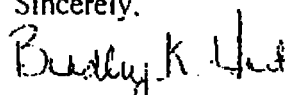
suspension should be terminated. Your rebuttal statement and any pertinent evidence should be sent to:

Bradley K. Hart, Inspector General  
The Office of Inspector General  
404 North Fifth Street, Springfield, Illinois 62706  
E-mail to [oitwebmaster@illinois.gov](mailto:oitwebmaster@illinois.gov).

Upon receipt of your rebuttal statement and any supporting evidence, OIG will make a determination to either continue or terminate the suspension and will provide written notice of its determination. This notice will contain specific findings on the conditions by which your suspension is continued or terminated.

If you have any questions concerning this action, please contact Trish Phillips at (217) 524-6119.

Sincerely,

A handwritten signature in black ink that reads "Bradley K. Hart". The signature is written in a cursive style with a large initial "B".

Bradley K. Hart  
Inspector General



**Office of Inspector General**  
***Illinois Department of Healthcare and Family Services***  
401 S. Clinton, 6<sup>th</sup> floor  
Chicago, IL 60607

Pat Quinn  
*Governor*

Bradley K. Hart  
*Inspector General*

February 27, 2013

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
Chicago, [REDACTED]

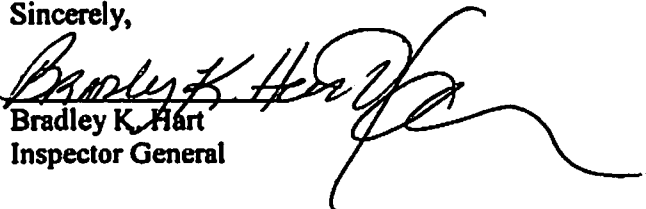
Re: Michael Reinstein

Dear Mr. [REDACTED]:

As noted in the November 16, 2012 letter to Dr. Reinstein payments were suspended due to a credible allegation of fraud. After full consideration of your request to release the withholding of payments the Office of Inspector General is unable to approve your request and will continue the withholding of payments.

If you have any questions, or you wish to respond, you may contact Kathleen McGinty at (312) 793-2664.

Sincerely,

  
Bradley K. Hart  
Inspector General





Kathleen Breidert  
Acting Director

## Illinois Department of Public Aid

Jesse B. Harris Building  
100 S. Grand Avenue East  
Springfield, Illinois 62762-0001

September 12, 1988

Michael Reinstein, M.D.  
[REDACTED]  
[REDACTED]

Re: 85 MVH 84

Dear Dr. Reinstein:

I have reviewed the attached Recommended Decision of Hearing Officer John T. Riley relating to your administrative proceeding before the Illinois Department of Public Aid.

I agree with Hearing Officer Riley that recovery is warranted. Accordingly, I adopt Hearing Officer Riley's findings of fact, conclusions relating to recovery, and recommendation relating to recovery. This means that you owe the Department of Public Aid the sum of \$8,857.27. Unless satisfactory arrangements are made for payment of this sum, the Department will initiate legal action to recover it.

With regard to termination, I do not believe that the violations at issue, the two altered charts, warrant the sanction of termination. The violations are serious, but the number is minimal. I believe that a one year suspension is adequate to address these violations. Accordingly, you are suspended from the Medical Assistance Program for a period of one year. The suspension shall begin on the date you receive this letter and continue for one year. Pursuant to Section 140.19(b) of the Department's rules, at the end of the period of your suspension, you will be reinstated to the Medical Assistance Program upon completion of the necessary enrollment forms, unless it is determined that you have not corrected the deficiencies upon which the suspension is based.

This is the final and binding administrative decision of the Illinois Department of Public Aid.

Sincerely,

Kathleen Breidert

KB:pn

Attachment

cc: Bernard J. Kayne  
Mark Anderson

**STATE OF ILLINOIS**  
**DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION**  
**DIVISION OF PROFESSIONAL REGULATION**

DEPARTMENT OF FINANCIAL AND  
PROFESSIONAL REGULATION

of the State of Illinois,

v.

Michael J. Reinstein, M.D.,

License No. 036-041796,

Complainant,

Respondent.

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No. 2012-

1152

CLERK OF THE COURT

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ILL. DEPT. OF FINANCIAL AND  
PROFESSIONAL REGULATION

**NOTICE OF PRELIMINARY HEARING**

To: Michael J. Reinstein, M.D.  
8928 Kilpatrick Ave  
Skokie, IL 600761828

PLEASE TAKE NOTICE that on **DECEMBER 17, 2012 at 1:00 p.m.**, you are directed to appear before the Administrative Law Judge of the Department of Financial and Professional Regulation of the State of Illinois (the "Department") located at 100 West Randolph Street, Suite 9-300, Chicago, Illinois 60601, at which time a hearing date will be set. You are requested to then and there present any and all routine motions you may wish to have heard regarding the charges contained in the attached Complaint. Any motions presented on the above date should be served on the Adjudicative Services Unit of the Department of Financial and Professional Regulation, Division of Professional Regulation, 100 West Randolph Street, Suite 9-300, Chicago, Illinois 60601 at least three (3) business days in advance of the scheduled hearing.

Your appearance on the scheduled date and time is mandatory and your failure to so appear may result in the selection of a hearing date in your absence, unless a continuance has been secured in advance. Your appearance may be made personally or through counsel.

It is required that you file a Written Answer to the attached Complaint under oath and penalty of perjury with the Department within twenty (20) days after this notice was mailed. The Answer should address each numbered paragraph of the Complaint. The Answer shall be signed under oath and your signature must be verified by a notary public who affixes the notary seal to the document. For each paragraph of the Complaint, the Answer should either:

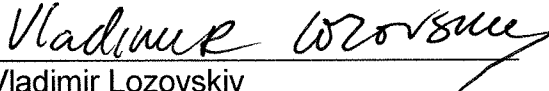
- a) admit the allegation in the paragraph;
- b) deny the allegation in the paragraph;
- c) state under oath that you have insufficient information with which to admit or deny the allegation in the paragraph.

PLEASE BE ADVISED that failure to file a verified Answer may subject you to being held in default. If you are held in default, the Board will assume the allegations of the Complaint to be true and will issue recommendations based on the facts without a Formal Hearing being held. These proceedings are pursuant to the jurisdiction granted to the Department to investigate complaint and to bring this action pursuant to 20 ILCS 2105-15(a)(5) and 225 ILCS 60/36.

RULES OF PRACTICE IN ADMINISTRATIVE HEARINGS IN THE DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION AND BEFORE COMMITTEES OR BOARDS OF SAID DEPARTMENT AS WELL AS PRACTICE ACTS AND RULES MAY BE OBTAINED AT THE DEPARTMENT'S WEBSITE <http://www.idfpr.com/dpr/default.asp>

PLEASE BE ADVISED THAT YOU WILL HAVE TO SHOW A STATE ISSUED PHOTO IDENTIFICATION AND GO THROUGH A METAL DETECTOR IN ORDER TO GAIN ACCESS TO THE BUILDING.

**DEPARTMENT OF FINANCIAL AND  
PROFESSIONAL REGULATION of the State of  
Illinois; Division of Professional Regulation**

  
Vladimir Lozovskiy  
Attorney for the Department

Vladimir Lozovskiy  
Staff Attorney, Medical Prosecutions Unit  
Department of Financial and Professional Regulation  
State of Illinois  
100 West Randolph Street, Suite 9-300  
Chicago, Illinois 60601  
312/814-1691

State of Illinois

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County of Cook

)

SS: 2012-11524

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UNDER PENALTY of perjury, as provided by law pursuant to Section 1-109 of the Illinois Code of Civil Procedure, the undersigned certifies that I cause the attached COMPLAINT AND NOTICE OF PRELIMINARY HEARING to be deposited in the United State mailbox located at 100 West Randolph Street, Suite 9-300, Chicago, Illinois 60601 and by mailing same by CERTIFIED mail at 100 West Randolph Street, Suite 9-300, Chicago, Illinois 60601, before 5:00 pm with proper postage prepaid on the \_\_\_\_ day of \_\_\_\_\_, 2012 to all parties at the addresses listed on the attached documents.

\_\_\_\_\_  
Affiant

\_\_\_\_\_  
Certified Mail Article Number

**STATE OF ILLINOIS  
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION  
DIVISION OF PROFESSIONAL REGULATION**

DEPARTMENT OF FINANCIAL AND  
PROFESSIONAL REGULATION  
of the State of Illinois,

Complainant,

v.

Michael J. Reinstein, M.D.,  
License No. 036-041796,

Respondent.

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) No. 2012-1114

CLERK OF THE COURT

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ILL. DEPT. OF FINANCIAL AND  
PROFESSIONAL REGULATION

**COMPLAINT**

NOW COMES the DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, DIVISION OF PROFESSIONAL REGULATION, of the State of Illinois, by its Chief of Medical Prosecutions, Laura E. Forester, and as its COMPLAINT against Michael J. Reinstein, M.D., Respondent, complains as follows:

**COUNT I**

1. Respondent is presently the holder of a Certificate of Registration as a Physician and Surgeon in the State of Illinois, License No. 036-041796 issued by the Department of Financial and Professional Regulation of the State of Illinois. Said licenses are presently in Active status.
2. That the Department has jurisdiction to investigate complaints and to bring this action pursuant to 225 ILCS 60/36.
3. At all relevant times, Respondent was practicing as a Physician and Surgeon in the State of Illinois.
4. At all relevant times, Respondent was practicing as a Physician specializing in the field of Psychiatry.

5. At all times herein mentioned, Respondent provided treatment and care to mentally ill patients residing in approximately 30 (thirty) different nursing homes in Chicago and its surrounding area.
6. At all times herein mentioned, Respondent routinely and continuously prescribed various psychiatric medications, including atypical antipsychotics, such as Clozapine (also known by its brand name Clozaril), to multiple patients of his practice.
7. Clozapine is primarily used for treatment of the symptoms of schizophrenia.
8. Clozapine is known to cause life-threatening side effects, including but not limited to:
  - a. Agranulocytosis;
  - b. Seizures;
  - c. Myocarditis;
  - d. Increased mortality in elderly patients.
9. Clozapine is considered to be a drug of last resort, particularly for elderly patients.
10. Respondent knew and/or should have known about life-threatening side effects of Clozapine.
11. Respondent knew and/or should have known that Clozapine is considered to be a drug of last resort for elderly patients.
12. Prior to August 2003, Respondent continuously prescribed Clozaril (brand name of Clozapine) to multiple patients under his care and treatment.
13. Prior to August 2003, Respondent received financial compensation from the manufacturer of Clozaril.

14. Prior to August 2003, Respondent prescribed Clozaril to approximately 1000 (one thousand) patients under his care and treatment, despite the potential life-threatening side effects and Clozapine's status as a drug of last resort.
15. Prior to August 2003, Respondent was the largest prescriber of Clozaril to patients who were receiving Medicaid in the United States.
16. In 2000 and 2001, Respondent prescribed more Clozaril to his Medicaid patients than the next nine top Clozaril-prescribing physicians in the United States combined.
17. On or about August 2003, Respondent stopped receiving financial compensation from the manufacturer of Clozaril.
18. Prior to August 2003, Respondent did not prescribe Clozapine, which is a generic form of Clozaril, to multiple mentally ill patients of his practice.
19. On or about August 2003, Respondent began prescribing generic Clozapine to multiple mentally ill patients of his practice.
20. On or about August 2003, Respondent agreed to prescribe generic Clozapine to multiple mentally ill patients of his practice in exchange for receiving a \$50,000 one-year consulting agreement from IVAX, the manufacturer of generic Clozapine.
21. Beginning August 2003, Respondent became the largest prescriber of generic Clozapine in the United States.
22. Beginning August 2003, Respondent prescribed generic Clozapine to more than 50% of the patients under his care and treatment.

23. While Respondent was prescribing Clozapine to more than 50% of the patients under his care and treatment, approximately only 4% of all schizophrenia patients in the United States were prescribed Clozapine.
24. On or about August 2004, Respondent requested and received an additional \$50,000 one-year consulting agreement from IVAX, the manufacturer of generic Clozapine.
25. On or about October 2005, Respondent requested and received an additional \$50,000 one-year consulting agreement from IVAX, the manufacturer of generic Clozapine.
26. While Respondent was prescribing Clozapine to multiple mentally ill patients under his care and treatment, Respondent received additional direct and indirect remuneration from IVAX, the manufacturer of generic Clozapine, including but not limited to:
- a. Free travel and lodging accommodations to IVAX's headquarters in Miami for Respondent and his multiple guests in February 2004;
  - b. Free fishing trip for Respondent and his multiple guests in February 2004;
  - c. Free dinner(s) for Respondent and his multiple guests in February 2004;
  - d. Free medications for Respondent's personal use;
  - e. Free travel and lodging accommodations to IVAX's Miami headquarters for Respondent and his multiple guests in March 2005;
  - f. Free boat cruise for Respondent and his multiple guests in March 2005;
  - g. Free dinner(s) for Respondent and his multiple guests in March 2005;



- h. Free tickets to one or more sporting events for Respondent and his multiple guests between 2003 and 2006.
27. On or about January 2006, IVAX merged with, and became a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.
  28. On or about April 2007, Respondent requested and received an additional \$50,000 one-year consulting agreement from Teva, the manufacturer of generic Clozapine, that was made retroactive to November 2006.
  29. On or about June 2008, Respondent requested and received an additional \$50,000 one-year consulting agreement from Teva, the manufacturer of generic Clozapine.
  30. On or about June 2009, Respondent requested and received an additional \$50,000 one-year consulting agreement from Teva, the manufacturer of generic Clozapine.
  31. On or about Fall of 2009, Respondent requested Teva to stop his consulting agreement after an article appeared in the Chicago Tribune questioning the appropriateness of Respondent's prescribing of Clozapine to multiple mentally ill patients under his care and treatment.
  32. Between 2003 and 2009, Respondent continuously prescribed generic Clozapine to multiple mentally ill patients under his care and treatment without taking into consideration the alternative treatment options.
  33. Between 2003 and 2009, Respondent continuously prescribed generic Clozapine to multiple mentally ill patients under his care and treatment disregarding patient's well being due to severity of potential life-threatening side effects of Clozapine.

34. Between 2003 and 2009, Respondent continuously prescribed generic Clozapine to multiple mentally ill patients under his care and treatment while receiving illegal direct and indirect remuneration from manufacturer of generic Clozapine in the United States.
35. Between 2003 and 2009, Respondent continuously prescribed generic Clozapine to multiple mentally ill patients under his care and treatment while receiving \$50,000 consulting agreements from the manufacturer of generic Clozapine in the United States in the following years:
- a. 2003;
  - b. 2004;
  - c. 2005;
  - d. 2006;
  - e. 2007;
  - f. 2008;
  - g. 2009.
36. The foregoing acts and/or omissions are grounds for revocation or suspension of a Certificate of Registration pursuant to 225 Illinois Compiled Statutes, Section 60/22 (A), paragraph (5), relying upon the Rules for the Administration of the Medical Practice Act, Illinois Administrative Code, Title 68, Chapter VII, Subpart b, Part 1285.240 (a) (1) and (2).

WHEREFORE, based on the foregoing allegations, the DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, DIVISION OF PROFESSIONAL REGULATION, of the State of Illinois, by Laura E. Forester, its

Chief of Medical Prosecutions, prays that the Illinois Physician and Surgeon License of Michael J. Reinstein, M.D., be suspended, revoked, or otherwise disciplined.

**COUNT II**

1-35. The Department realleges paragraphs 1 through 35 of Count I as paragraphs 1 through of Count II.

36. The foregoing acts and/or omissions are grounds for revocation or suspension of a Certificate of Registration pursuant to 225 Illinois Compiled Statutes, Section 60/22 (A), paragraph (18).

WHEREFORE, based on the foregoing allegations, the DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, DIVISION OF PROFESSIONAL REGULATION, of the State of Illinois, by Laura E. Forester, its Chief of Medical Prosecutions, prays that the Illinois Physician and Surgeon License of Michael J. Reinstein, M.D., be suspended, revoked, or otherwise disciplined.

**DEPARTMENT OF FINANCIAL AND  
PROFESSIONAL REGULATION, DIVISION OF  
PROFESSIONAL REGULATION, of the State of  
Illinois**

By: 

\_\_\_\_\_  
Laura E. Forester  
Chief of Medical Prosecution

Vladimir Lozovski  
Staff Attorney, Medical Prosecutions Unit  
Department of Financial and Professional Regulation  
Division of Professional Regulation  
100 West Randolph, Suite 9-300  
Chicago, Illinois 60601  
312/814-1691